K014156

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curasan

510 (K) Summary
Cerasorb ORTHO Synthetic Bone Void Filler

Submitted by

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Prepared:
Curasan AG

	Subject Device	Predicate Device
Trade name	Cerasorb ORTHO	Vitoss™ Scaffold Synthetic
Common Name	Bone void filler	Bone void filler
Classification Name	Filler, ß-Tricalciumphosphate Preformed granules	Filler, ß-Tricalciumphosphate Preformed granules

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Comparison To Predicate
Tabulated Form

	Cerasorb ORTHO	Vitoss™ Scaffold
Indication / intended use	Bone void filler, synthetic	Bone void filler, synthetic
Patient population	Patients with bone voids or gaps, caused by surgery, trauma or degeneration	Patients with bone voids or gaps, caused by surgery or trauma
Anatomical location	skeletal system (extremities, spine, pelvis)	skeletal system (extremities, spine, pelvis)
Labeling	Same intended use, contraindications, warnings, precautions and adverse events as predicate	see enclosure
Chemical composition of the material	ß-Tricalciumphosphate, $Ca_3(PO_4)_2$	ß-Tricalciumphosphate, $Ca_3(PO_4)_2$
Structure of the material	Interconnective porosity	Trabecular structure similar to cancellous bone
Porosity of the material	Micropores >0<80µm	Pore size 1 – 1000 µm
Performance • Osteoconductivity • Resorption • Bone remodeling • Mechanical properties	+ + + Granules have no weight-bearing capacity. Execution of osteosynthetic measures eventually necessary	+ + Does not import mechanical strength to surgical site
Sterility	Sterile (gamma radiation) Single use only	Sterile (gamma radiation) Single use only
Biocompatibility	Established	Established
Presentation	Granules, sizes: • 500 – 1000 µm • 1000 – 2000 µm	Morsels (1-4mm sizes) and blocks (9x23mm cylinder)

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Device description

Cerasorb ORTHO is a porous resorbable bone void filler for the repair of bony defects. Chemically the material consists of pure phase Beta-Tricalciumphosphate, as described in the ASTM F 1088 – 87 (reapproved 1992). It is an osteoconductive implant with interconnected porosity. The implant is provided sterile in granular form, granular sizes being 500 – 1000µm or 1000 – 2000 µm.
When Cerasorb ORTHO is placed in the defect site with direct contact with the viable host bone, it guides the three-dimensional regeneration of bone. As the Cerasorb ORTHO granules resorbs, newly formed bone grows into the space previously occupied by the granular Beta-Tricalciumphosphate material. Cerasorb ORTHO was shown to have 90% or greater resorption in animal studies and was also shown to resorb well clinically.

Intended use

Cerasorb ORTHO in granular form is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structures. It is indicated for filling of bone defects, caused by surgery, trauma or degenerative process. Cerasorb ORTHO granules are intended to be gently packed into the bony voids or gaps of the skeletal system. The material should not be packed in dry form, it should be mixed with autologous blood (blood from the void or venous blood). The implanted material must be in direct contact with the bleeding vital bone.
Cerasorb ORTHO granules have no weight-bearing capacity. Therefore, osteosynthetic measures may be required.
Following placement in the bony voids or gaps, the Beta-Tricalciumphosphate granules are gradually resorbed and substituted by vital, natural bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

Curasan AG
c/o Arrowsmith-Lowe Consulting, Inc.
5 Eagle Creek Road
P.O. Box 3148
Ruidoso, New Mexico 88355
Attn: Thomas Arrowsmith-Lowe

Re: K014156
Cerasorb ORTHO
Regulatory Class: unclassified
Product Code: MQV
Dated: December 18, 2001
Received: December 19, 2001

Dear Dr. Arrowsmith-Lowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K014156

Device Name: Cerasorb ORTHO

Indications For Use:

Intended use

Cerasorb ORTHO in granular form is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structures. It is indicated for filling of bone defects, caused by surgery, trauma or degenerative process. Cerasorb ORTHO granules are intended to be gently packed into the bony voids or gaps of the skeletal system. The material should not be packed in dry form, it should be mixed with autologous blood (blood from the void or venous blood). The implanted material must be in direct contact with the bleeding vital bone.
Cerasorb ORTHO granules have no weight-bearing capacity. Therefore, osteosynthetic measures may be required.
Following placement in the bony voids or gaps, the Beta-Tricalciumphosphate granules are gradually resorbed and replaced with new bone.

(PLEASE DO NOT WRITE BELOW THIS LINE-CCONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of CDevice Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014156

(Optional Format 3-10-98)